EXHIBIT A

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF WEST VIRGINIA

AT CHARLESTON

IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	:	MASTER FILE No. 2:12-MD-02327
THIS DOCUMENT RELATES TO ALL WAVE 3 CASES	:	MDL 2327 JOSEPH R. GOODWIN US DISTRICT JUDGE

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August 29, 2016

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DEPOSITION of JERRY G. BLAIVAS, M.D., commencing at 12:00 p.m. on the above date at Urocenter of New York, 445 East 77th Street, New York, New York, before Marie Foley, a Registered Merit Reporter, Certified Realtime Reporter and Notary Public of the State of New York.

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GOLKOW TECHNOLOGIES, INC.

877.370.3377 ph | 917.591.5672 fax

Deps@golkow.com

A P P E A R A N C E S:

MOTLEY RICE, LLC
BY: FIDELMA L. FITZPATRICK, ESQUIRE
321 South Main St., 2nd Floor
Providence, RI 02903
401.457.7700
ffitzpatrick@motleyrice.com
Representing the Plaintiff

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are not caused by the polypropylene midurethral sling?
A. Yes.
Q. And it's fair to say that in your clinical practice, there are times that you diagnose women's complications as being related to the polypropylene midurethral sling that they have?
A. Yes.
Q. When a woman presents to you with a complication that you then determine after examination is caused by a midurethral sling, what treatment options do you offer to that woman?
A. Well, it depends what the complication is. Generally, and these are very -- you know, it depends what the complication is. If it's clearly an obstruction from the sling, and when there is an obstruction that's what it usually is, then my recommendation is that we remove the entire suburethral portion of the sling.
If the complication is a

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fistula, then we remove all of the sling, all of the sub -- all of the sling that's in the vicinity of the urethra -- excuse me, of the fistula and then repair the fistula.
If it's pain, then it depends where the pain is, and again I don't have to go into the particulars, but sometimes we just remove that portion that appears to be related or causing the pain, but sometimes we remove the entire mesh 'cause I think the entire mesh is causing the pain.
If it's overactive bladder symptoms, we -- if it's due to urethral obstruction, we remove the suburethral portion. If we're not -- if it seems like it's in the wall of the bladder but -- or through the wall of the bladder, then we remove all of the sling on that side and sometimes the entire sling.
Q. Is it fair to say based on what you've just told me that the treatment options that you offer are tailored to a

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woman's specific problems?
A. Of course.
Q. And would you say that you try to treat the problems as conservatively as possible, with the least amount of surgery necessary to correct those problems?
A. No, I would say I try to be appropriate. I mean, sometimes it's appropriate to be conservative. Sometimes it's appropriate to be radical, but I discuss it with the patient.
Q. Okay. Now, in addition to your clinical work and your clinical experience, you also have done academic work and published articles concerning mesh and mesh complications, correct?
A. I have.
Q. And most recently you published an article entitled "Safety Considerations for Synthetic Sling Surgery" that was published in the Nature Reviews of Urology in 2015, correct?
A. Yes.
Q. And you were a co-author on that

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with eight other individuals, correct?
A. Yes.
Q. Can you tell me, first of all, how this article came to be?
A. Well, Nature Reviews in Urology is a highly respected peer review journal, and they, for their reviews they actually solicit authors. I don't believe you can just submit. I'm not sure of that.
But they asked me to do a review article, and they told me right up front that just because I agreed to do it, it did not mean that it would be automatically accepted.
Q. Now, can you tell us what a review article is?
A. A review article is, there are lots of different types, but basically it's a compilation of many and sometimes all of the articles in the peer review literature about a certain topic. And then, so the first thing that you do is you -- is you do a literature search and you identify the articles and then you use

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search criteria to eliminate certain articles and then you analyze them based on whatever methodology you choose.
Q. So, let me discuss, you were approached by Nature and asked to conduct a review on the literature available concerning synthetic sling surgery, correct?
A. Yes.
Q. And, I see that we mentioned you have a number of other authors here.
Are those authors that you asked to help you with this, or are those authors that Nature assigned to this project?
A. No, I got to select my team.
Q. Can you tell me how you went about selecting the team?
A. Sure. Well, okay, so, two of the co-authors, Robert Bendavid and Vladimir Latovlev, L-A-T-O-V-L-E-V, are recognized authorities in the field, and I asked them if they would be willing to help me with this.

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One of them, Roger Purohit, P-U-R-O-H-I-T, is my partner, so we operate together and he has a considerable amount of clinical experience. And then Matt Benden and Gabriel Mekel, M-E-K-E-L, and Michael Stern and Mubashir Billah, B-I-L-L-A-H, and I'll have to spell the other ones, K-O-L-A is the first name and it's O-L-U-G-B-A-D-E, were all students that -- well, actually, Dr. Mekel was doing a fellowship with me and the others are either medical students, or are all medical students.
Q. Okay. When did Nature approach you about authoring a review on synthetic sling surgery?
A. It was some time after May of, I guess, 20 -- I don't know if it was 2013 or -- probably -- or 2014. I can't remember.
Q. Okay.
A. But it was after the American Urologic Association national meeting.
Q. Did anyone from Nature tell you

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why they selected you or asked you to write this article over others?
A. Well, yes, they had heard -- one, they heard about me, they knew of me and they asked around and they asked who would be a good person to do it, and I believe someone had seen me participate in a debate at the annual meeting of the American Urologic Association.
Q. Was there any kind of preconceived outcome that anyone had discussed with you of what they expected your research to show or not show?
A. No.
Q. Now, this article that you did, a review article, does not contain all of the articles available in the medical literature that reference or concern midurethral slings, correct?
A. Correct.
Q. How did you and your co-authors determine and choose the articles that you relied on for this particular piece?
A. Well, two ways. One, and I'm

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sorry, I don't have all the details in my memory, but there was an article published -- there was another review article that I thought was timely that did a review up to a certain date and then we -- I just decided to do it from about that time to the what was then current, which was 2014. And I can tell you in a minute what the dates were.
Q. Sure.
(Pause.)
A. So, it was from 2007 to 2014.
Excuse me, that was for the clinical review, okay. Dr. Latovlev independently reviewed the pathology which went back many years before that.
Q. One of the things that I want to talk to you about today is the conclusions that you reached concerning the complications and the complication rates associated with midurethral slings.
Would that be included in the clinical review that you just mentioned?
A. Yes.

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Q. So, you and your co-authors chose articles written from 2007 to 2014, and I think what you mentioned to me before was that there's certain search criteria that you use when conducting your literature search to determine what articles would be included in a review article; is that right?
A. Yes.
Q. And can you tell me what the search criteria that you and your co-authors were?
A. It's a long list. Shall I read it to you?
Q. Sure.
A. Okay. So, the search combined the terms, and some of these are just spelling things. So, there was midurethral slings where "mid" and "urethral" are two words; midurethral slings where "midurethral" is one word; suburethral sling, urethral sling, midurethral slings with a plural, both words again with a plural. All of the

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words that I just said also in plural. Follow-up study, other than all of those terms and follow-up study.
Also, we used free text searches including the terms urinary incontinence -- excuse me, TVT, tension free vaginal tape, tension free vaginal sling, transobturator tape, transobturator sling, TVT-Obturator, TVT-O, TVT Secure, Minarc, that's M-I-N-A-R-C, Abbrevio, A-B-B-R-E-V-I-O, TOT, suprapubic arc sling, Sparc, S-P-A-R-C, sling, intravaginal slingplasty, IVS sling, RAZ, R-A-Z, sling, Uratape, that's U-R-A-T-A-P-E, ObTape, O-B-T-A-P-E, prepubic sling, prepubic TVT, prepubic tape, Pelvilace, P-E-L-V-I-L-A-C-E, ureter, Aris, A-R-I-S, In-Fast, I-N-F-A-S-T, Monarc I-STOP, urethral reconstruction, urethral vaginal fistula, other spelling of ObTape, Gore-Tex sling, silastic sling, Mersilene sling, Marlex sling, vesicovaginal fistula, Bioarc. And then -- yeah, so that was the search that

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we did on the clinical end.
Q. Okay. And that sounds like quite a number of search terms; is that right?
A. Yes.
Q. Why did you have so many search terms?
A. 'Cause we didn't want to miss any articles, and what we did is we would look up -- we started with less search terms and as we read articles, we would see synonyms or new words and then we would add that to the search term.
Q. Did you limit the types of articles you were looking at? For example, did you only look at randomized control trials or only look at meta-analyses or only look at case studies?
A. No, we did not limit it.
Q. Is it fair to say that you were trying to get as big a cross-section or as big a representation of all of the articles out there and kind of gather them

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up before you got started with this process?
A. Yes. I just remembered there was actually, there was one exclusion criteria that we used. If an article by the same authors seemed to include the same patients in a different study, we would have used the most -- either the most recent one or the most appropriate one. We tried not to count the same patients twice.
Q. Okay.
A. So if one author had a patient -- had a study that showed the patients at one year, five years, 10 years, 15 years and 20 years, and they had complications, we wouldn't count the complications five times. We'd only count the complications once.
Q. Okay. Is it fair to say that you were attempting to count each patient one time and not duplicate those patients or those complications in your analysis at all?

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A. Exactly.
Q. And the method that you used to do that by only using one article from a series, is that a standard acceptable way of achieving that goal when doing medical or scientific research?
A. You know, I don't know.
Q. Tell me why you thought that it was an appropriate way to achieve that result.
A. Because I wanted to be sure on the one hand that we captured every complication, but on the other hand we didn't count anybody twice 'cause we were looking to get as precise a number for both -- for complications as we could. We didn't want to overestimate; we didn't want to underestimate.
Q. Okay. And that's for the clinical portion, and clinically you looked at both the safety of the product, correct, the complications?
A. Yes.
Q. And you also looked at the

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efficacy of the product, correct?
A. Yes.
Q. Was there different criteria that you looked at for articles relating to efficacy?
A. Yes. For articles for efficacy we only included those articles that measured efficacy, that had appropriate follow-up, and we did have criteria for that.
Q. Is that different from -- it sounds like you had more exclusion criteria for the efficacy articles than you did the complication/safety articles; is that right?
A. Yes.
Q. Is there anything else that you excluded beyond, from your literature search, beyond the subsequent articles or the multi-reported cases?
A. Yes. The only other exclusion was non-human subjects.
Q. Did you in any way cherry pick or look only for reports or articles that

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dealt with high rates of complications?
A. No.
Q. Did you only look for articles that reported low rates of complications?
A. No. We intend -- to the best of our ability, we picked every article in the literature in that time period.
Q. And that are articles that reflected some lower rates of complications, correct?
A. Of course.
Q. And articles that reflected higher rates of complication, correct?
A. Yes.
Q. And fair to say it included case studies?
A. Yes, it did.
Q. It included randomized control trials?
A. Yes.
Q. It included meta-analyses?
A. Yes.
Q. Is there anything at all that you or your co-authors did to limit or

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exclude certain articles or certain findings in articles that would otherwise have been encompassed in your search terms?
A. Only for the efficacy studies.
Q. Okay. Now --
A. And that -- but those were a search term, so we -- so I guess the answer is no, we did not. Okay.
Q. Now, could somebody look at what you've reported in Table 1 relating to the efficacy issues and extrapolate in any way what you did there and apply it to the complication tables that you reflected in Table 2, 3, 4 and 5?
A. No, you couldn't because they didn't apply -- none of these -- well, most of these studies did not have any scientifically valid prospective way of looking at complications. This was just for efficacy.
Q. Is there any way that someone could --
MS. FITZPATRICK: Let me ask it

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a different way.
Q. Is it correct that there are articles that you considered for your safety considerations or complication rates that are not reflected in the table concerning efficacy?
A. Probably not because we would always -- no, because we would -- we would -- if there was even one complication, we would -- we would have included it.
Q. But just because you had it, and I think what you're telling me is all of your efficacy articles were included in your complication analysis, and I'm actually asking the opposite.
Were all of the articles that you considered for the complication part all used also to look at efficacy?
A. No.
Q. So you can't say that simply because something isn't on the Table 1 that you didn't rely on it, use it, conclude anything about it or consider it

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as part of your safety considerations and complication considerations; is that right?
A. To the contrary; we would have used it.
Q. Okay. Now, this article went through the peer review process, correct?
A. Very much so.
Q. Can you tell me what you mean by that?
A. Well, the peer review process itself is designed to insure that the highest standards of scientific methodology were used in the paper and very specifically that the results and the conclusions follow from the methodology; i.e. that the conclusions follow from the methods.
Q. Is there anything that was different about the Nature peer --
MS. FITZPATRICK: Strike that.
Q. You've worked as a peer reviewer before, correct, for other journals?
A. Yes.

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Q. And you've also been editor of a journal that is a peer review journal, correct?
A. Yes.
Q. Can you tell me generally in the medical and scientific community how individuals get selected as peer reviewers?
A. Sure. They get selected by a process of usually by a committee of experts that picks other experts that they think contribute to the peer review process. So they have to show -- they have to be held in high regard as experts that can give a fair and unbiased appraisal of submissions.
Q. Do you know of any peer review publication that has considered the opinions of attorneys from medical device manufacturers as part of peer review process?
A. No, I do not.
Q. Why aren't attorneys for medical device manufacturers qualified to serve as

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peer reviewers for a medical journal?
A. Well, the most obvious reason is that their opinions were likely to be biased or that they have a major conflict of interest and they don't fulfill our criteria for being an expert. They're lawyers; they're not experts in scientific research.
Q. Is it fair to say that the peer review process is designed to have neutral, objective, experienced individuals assessing the methodology and the conclusions that are reached in medical and scientific journals?
A. Of course.
Q. That process is designed to insure that the methodology that is used is something that is recognized and acceptable in the medical and scientific community, correct?
A. Yes.
Q. In your experience as both a peer reviewer and as an editor of a peer review journal, what happens in the

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process if an article is presented that does not use established accepted methodology in the scientific and medical community?
A. Well, as a general rule, it's rejected. On rare occasions, someone comes up with such a novel approach that even though that it wasn't known before, it might become -- it might be acceptable.
Q. Do you believe that the peer review -- let me ask you this.
Tell me about the peer review process that you went through for your Nature article.
A. This was the most rigorous peer review that I've ever been part of. I mean, we -- this article took more time and more effort than any article I've ever written, and I, you know, I've done hundreds and hundreds. So it was a very labor intense project. We read all of the articles, and then when we wrote the articles, we submitted it and they had a number of questions, concerns, suggested

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revisions and it went back and forth a number of times to be sure that we -- that our -- to be sure, quite honestly, that our, as I mentioned a few minutes ago is that our results and conclusions were clearly supported by the methodology and that they were scientifically sound.
Q. Do you believe, Doctor, that the fact that your article in Nature Review survived the peer review process establishes that the methodology that you and your co-authors used in that, in drafting that article, was scientifically reliable?
A. I do.
Q. Would it be widely considered in your medical community that an article such as yours that has gone through such a rigorous peer review process has demonstrated appropriate medical and scientific methodology?
A. Yes.
Q. Has anybody in the medical community or at Nature questioned your

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methodology in connection with that article at any time prior to its publication?
A. Well, they asked questions about it in the review process, but I don't -- but afterwards, no, I don't -- I'm not aware of anybody questioning it.
Q. And are you comfortable that the Nature Review Urology looked closely at the methodology that you and your co-authors used to reach the conclusions that you did in that review paper?
A. I'm quite confident of that.
Q. We're going to talk in a little bit specific about some of the conclusions in that article and I'm going to ask you more specifically how you reached the conclusions that you did.
But, in addition to the conclusions that you reached in that article, you also rely on your clinical experience for an independent basis of your TVT-Exact report, correct?
A. Yes.

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Q. And including those portions that overlap with the other polypropylene midurethral sling products that you've offered reports on, correct?
A. Yes.
Q. In addition to your Nature article, in addition to your clinical experience, did you also rely on peer-reviewed literature which was identified both in the footnotes of your report and then in the reliance list that you provided with that report?
A. I did.
Q. In selecting that peer-reviewed literature for inclusion in your report or your reliance list, were there any articles that you just dismissed out of hand and refused to consider when reaching the opinions that you have in this case?
A. I don't dismiss them out of hand. I mean, there's some that I don't agree with the methodology.
I mean, are you asking in general?

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Q. Would you ever look at an article and say well, there's only a .1 complication rate, so I'm not even going to look or consider that article?
A. No, I don't do that.
Q. Tell me what you do when you look at articles to determine that you think, or what weight you should be giving to those particular articles.
A. Generally, first thing I do is look at the results of the -- basically I basically look at the conclusions first and then I look at the methodology and say -- confirm that the conclusions could be justified by the methodology. If the methodology is such that it can't even answer the questions that the conclusions concluded, I would still look at the paper, but I would -- I would tend to not read that in great depth. And then if the two go hand in hand, then I look at the results and make sure that the results follow from the methods as well.
Q. In your both clinical and

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academic practice, do you regularly and routinely read articles that appear in the medical and scientific literature about polypropylene slings?
A. I do.
Q. Are those also brought to your attention by colleagues of yours?
A. Yes.
Q. Do you consider all of those articles as part of --
MS. FITZPATRICK: Excuse me.
Q. Do you consider all of those articles prior to reaching the conclusions that you've set forth in your expert report?
A. I consider them, yes.
Q. Okay. Now, I want to ask you a couple of questions, specifically about what's in your report.
In paragraph 17 of your report that you have in front of you, you note that it is common for trocars to puncture the bladder or urethra during trocar passage.

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A. Yes.
Q. Do you see that?
A. I do.
Q. Looking at your Nature article, you also looked at incidents of bladder and transvaginal trocar perforation, some of the complications that were reported in the medical literature, correct?
A. I do.
Q. Let's start with do you rely on any of your clinical experience for your opinion that it is common for trocars to puncture the bladder or urethra during trocar passage?
A. I do.
Q. And how does your clinical experience specifically support your opinion that it is common for trocars to puncture the bladder or urethra during trocar passage?
A. Well, from my clinical experience, when I -- first of all, I talk to a lot of my peers and colleagues about it and I simply ask them in the hospital.

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I -- in over two thousand cases that I've done without mesh, there's only been one time that I perforated the -- the bladder, and when that happened, I was personally really taken aback and I kind of made a big deal about it. And the resident said, "What are you doing? Why are you so upset?" I said, "Geez, well, we just perforated the bladder." And the resident said, "Well, yeah, happens all the time with -- it happens all the time with the midurethral slings." That's one -- that's one point of information.
Second is, as I mentioned, I talk to my colleagues and my peers a lot about this stuff and they, virtually all of them, almost all of them say that it does happen periodically that they perforate the bladder.
Q. But --
A. And then --
Q. Sorry. Go ahead.
A. And then finally, I've seen hundreds of patients that have had

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complications from slings, and when I review those operative notes, they not infrequently say that they perforated the bladder.
Q. Okay.
A. And then took it out and passed it again.
Q. But you don't rely just on the anecdotal stories from colleagues or looking at your report to reach your opinion that it's common for trocars to puncture the bladder or urethra during passage, correct?
A. Of course not.
Q. What else do you rely on for that opinion?
A. On the published literature.
Q. Can you identify any peer-reviewed published literature that you have seen that you rely on to support your opinions that it's common for these punctures to happen?
A. Sure. There's an article by Albo, I think it was -- I think it was

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2012, that was reported in the Journal of Urology that found an incidence of, I forget the exact number, either five or six percent were perforated. And in the AUA guidelines, Roger Dmochowski published that in, he was the lead author, in 20 -- actually, I don't remember the year, but that also had a similar incidence of about five or six percent.
Q. Are those the only articles that you rely on?
A. No, there's many other ones.
Q. And are many of those articles also cited in your reliance list --
A. Yes.
Q. -- that you provided in this case?
A. Yes.
Q. Do you believe that there's sufficient peer-reviewed published literature to support the opinion that it's common for trocars to puncture the bladder or urethra during trocar passage?
A. Well, common is in the eyes of

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the beholder, but I think there's ample literature to show that it happens on the order of magnitude of five percent. In series it's as high as 20 or 30 percent.
Q. And is that something that you also looked at in connection with your Nature Review article?
A. Yes.
Q. Can you tell me what you did in your Nature Review article to look at this incidence of trocar puncture of the bladder or urethra?
A. Well, that we just compiled all the articles in the literature because there wouldn't be a case report -- all of the -- all of the articles that were reviewed and we just averaged the -- we gave a range and an average and a mean of how often it was perforated.
Q. Okay. So, let me stop you there because I want to talk a little bit more about the methodology that you used not just for calculating trocars, but for calculating all of the rates of

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complications.
Was bladder or urethra puncture during trocar passage one of the complications that you looked at and considered in your Nature Review article?
A. It was.
Q. What I'd like you to do is to walk me through you and your co-authors compile all of the literature that you can find from an extensive literature search that report any complications or any incident of complications from either an individual patient or a patient cohort; is that correct?
A. Yes.
Q. And you looked for everything you could find; is that right?
A. Yes.
Q. And you didn't exclude any articles unless it was a multiple reporting of the same cohort?
A. Or non-humans.
Q. Or non-humans, okay.
And your reason for excluding

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multiple reports of the same cohort is you didn't want to double count injuries, so therefore potentially inflating the rates of complications that you were looking at; is that right?
A. Yes.
Q. You were attempting to keep it one patient counted for one time throughout this analysis that you did, correct?
A. Yes.
Q. So you and your colleagues have this massive medical literature in front of you.
What did you do with that information to reach the conclusions that you reached in your article concerning the existence of certain complications and then the incidence of those complications?
A. Well, for the incidence we counted every single complication. So, to make it simple, if there were only two articles, one had a hundred patients and no, in this instance, perforations and one

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was a case report of one complication with no denominator because it's just a case report, we would use the one as the numerator and the denominator would be the 101.
Q. Okay.
A. But of course this was done in hundreds of papers, so it was much more complicated than that.
Q. So let me, as a non-scientist and non-medical person, let me see if I'm right in my understanding.
You took and counted every patient who was included in all of those articles and you counted them all up and that became your denominator, the total number of people who have been studied, reported, considered in some way in the medical literature as potentially, or as a subject in a study about mesh complications; is that right?
A. Yes.
Q. And then you took that entire denominator and then what you did is you

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went through and you added up each, for example in this case, each incident of bladder or urethral trocar perforation that you could find anywhere in that medical literature; is that right?
A. Yes.
Q. What did you do with those two numbers to reach the percentages in the conclusions that you reached?
A. Well, we just added them up. So the numerator is the number and the -- the numerator divided by the denominator is the percent.
Q. And that's the methodology that was reviewed by the neutral peer reviewers for Nature Journal of Urology, correct?
A. Yes. I mean, we also did -- we did it another -- the other way we did it is we looked at the range and the averages for each -- for when there's a -- when there were a series.
So, if there were two series and one had, you know, a hundred patients with zero perforations, another one had a

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hundred patients with 20 percent, you know, we would say that the range in the different series was zero to 20 percent and the mean of the series was whatever the numbers comes to.
Q. So you have two different ways that you've gone about this analysis and the two different methodologies.
The first is the adding up all of the individual women who are identified and doing the numerator and the denominator, and you did that specifically for each complication individually, correct?
A. Yes.
Q. So you'd calculate the number of women who had a bladder perforation separately from the number of women who had a urethral erosion, separate from the number of women who had a pain complication; is that right?
A. Yeah, we'd count each of them separately, yeah.
Q. And you also broke that down

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went about calculating the percentage of patients who have a potential complication based on what's available in the medical literature; is that right?
A. Yes.
Q. Now, the next column is "Incident mean range."
That's the second way that you went about also checking on the reports of complications and the incidence of complications, correct?
A. Yes.
Q. Can you explain to me how the methodology for reaching the incidence differs from the methodology used for reaching the complications?
A. Sure. In the first case, we counted every single patient, every single patient was counted once. In the incidence, where it says "Incidence mean and range," those -- that we only considered series of patients. So that doesn't include any of the patients with -- that were case reports. It

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doesn't include any of the patients, for example, that were just a paper on complications.
So the numbers in these two columns, even though they both represent means or averages, the numbers could be very different because they're different populations of papers.
Q. So, this was the way that you and your co-authors went about presenting the full gamut of information based on two statistical analyses, correct?
A. Exactly.
Q. And you reported on both the complications and the incidence without consideration to what was higher or lower? You made sure everything was reported here, correct?
A. Exactly.
Q. In some of these, the numbers are fairly comparable, right?
A. Yes.
Q. And in some of them there's some divergence in the percentage of patients

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that you had and the mean.
How do you account for that?
A. Because in the series, they may not have mentioned a certain complication. So for example, if you're looking at that same column, if you look at neurologic symptoms within six weeks, in the middle column we counted every single patient where they mentioned it. Now, it looks like there were only 42 patients in that particular group where they said these patients had these complications. Whereas in the other article, they could have had a paper with a thousand patients in it, but they didn't even mention whether or not there was a neurologic complication, so we couldn't count that.
Q. And in any event, let me look at the range. So, tell me what the range is.
A. Well, the range is -- describes what the minimum complication rate was in one series and the maximum in another -- in other series, and the reason that we did that is one of the critiques that you

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might apply to this kind of scientific literature is, well, if you just do an average -- if you just do an average, it doesn't tell you about the difference between perhaps, this is a perhaps, people that are really expert surgeons might get a zero complication rate and novices might, you know, get a 15 percent complication rates.
So this gives you the range of what you might expect with the same surgeon or groups of surgeons doing the operation.
Q. In looking at both your percentage of patients, as well as the mean that you have reported in this article, all of those fall within below the highest reported incident rate on the range; is that right?
A. Sure. That makes sense.
Q. So, does that reflect that your article is not reporting the highest possible rates of complications associated with any of these complications?

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A. To the contrary. We describe in the paper that we believe this represents the least possible number of complications.
Q. And it's well below --
MS. FITZPATRICK: Well, strike that. I think I already asked you that.
Q. Now, this methodology that you've just described, the two different types of methodology, you used that same methodology for each of the complications that you reported in this medical article; is that correct?
A. We did.
Q. Is it fair to say that this medical article is -- identifies all of the complications that you were able to see that are reported in the medical literature, correct?
A. From 2007 to 2014, yes.
Q. Now, what I want to ask you is you identify in your Nature Review article specific types of complications.
Are those complications that you

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have also seen with mesh synthetic sling patients in your clinical practice or through your academic experience?
A. Yes.
Q. In doing this work in 2014 and 2015, did you see any complications that were reported here that you didn't also have some clinical experience with?
A. Give me a moment.
(Pause.)
I'm amazed to say that no, I've seen every one of these complications.
Q. And do you rely on your clinical experience for your opinions that the TVT-Exact and the Ethicon midurethral slings can cause these types of complications in women?
A. They do.
Q. In addition to your clinical experience and in addition to what you have presented in the Nature Review article, do you also rely on other peer-reviewed literature from other authors to support your opinions that each

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of these complications is associated with the polypropylene midurethral slings?
A. I mean, it's not a question that the answer is "yes."
Q. Sometimes we ask stupid questions.
A. Okay.
Q. It's 'cause we have to.
Now, you walked me through the complication rates for retropubic slings, and what I want to talk to you about is your -- you've reached some opinions on the risk of negative outcome after synthetic midurethral sling implantation for surgery is greater than or equal to 15 percent.
Do you recall that?
A. I do.
Q. Can you tell me the methodology that you and your co-authors used to determine that the overall risk of a negative outcome after synthetic midurethral sling implantation surgery is greater than or equal to 15 percent?

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A. Sure. First we looked at the reported incidence that we already described. Then we took the chances of the failure of the sling, which would be a negative consequence. So we took the first number was the complications as we reported them. The second number was the chances of just failure, like any operation can fail. The third was the failure for stress incontinence after an operation -- after a complication from a sling, okay. And the fourth -- let me get my numbers right. I think it's the fourth. The fourth was the incidence of refractory overactive bladder, and what we did with that was that we made, again, a very conservative estimate, okay. So we took the number of reported de novo overactive bladder patients and we said that a certain percentage of them are likely to be refractory. And because the trouble is there is no data on that. There's no data that says, that we could find, that says that if you operate on

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them and they have de novo overactive bladder and you treat them, X number would get better. So I don't have the exact number, but we picked the number of de novo overactive bladder patients and then we took a percentage of that, of patients that are likely to be refractory, and when you add all those numbers up -- then we added a couple of -- there were a few things like bowel injuries and fistulas that are very rare, but we added in a number of that and added all of those up, the methodology, it's in the paper someplace.

Q. And that's the same methodology?

A. Yeah.

Q. Just so I understand, if I'm looking at box 1 on page 8 of your article.

A. Okay.

Q. It says: "Complications requiring surgery."

Is this the list of complications that you would consider a

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serious complication for the purposes of calculating that 15.3 percent number?

A. Yes.

Q. Is it fair to say that, or am I accurate in saying that that list of complications, plus the number of sling failures, the percentage of women whose slings simply don't work for them, you calculated that total --

A. No, no, that's in there. The recurrent and/or persistent stress incontinence.

Q. Okay.

A. That number is -- that's where the number comes from.

Q. Okay. Thank you for clarifying that.

So, when you say there's a total incidence of serious complications is 15.3 percent, is it accurate to say that's the calculation of the overall risk to a woman that one of these things could happen to her if she has a polypropylene midurethral sling implanted?

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A. I would say it another way. That there's a, I believe, at least a 15 percent chance of having a negative outcome from the sling, from putting the sling in.

Q. And the negative outcomes would be one of those things that you have identified in Box 1?

A. Yes.

Q. But it's not your testimony, for example, that 15.3 percent of women who have a midurethral sling will have chronic pain?

A. No.

Q. Or that 15.3 percent will have a urethral obstruction, correct?

A. Correct.

Q. It's just the overall chances of having one of these negative outcomes?

A. Yes.

Q. Now, going back in time, you published this article in late 2015; is that right?

A. Yes.

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Q. And it was based on medical records 2007 through 2014; is that right?

A. Yes.

Q. And do you recall that in the summer of 2014, you testified in front of Judge Goodwin in the Southern District of West Virginia in a case involving Mrs. Joe Husky; is that right?

A. I have a remote memory of it, yes.

Q. Well, I put you on the stand, so.

A. No, I did it.

Q. So I know that you did it.

And at that time, you had not done the statistical analyses and this analysis that's reflected in your Nature article, correct?

A. I'm sorry, what was the date?

Q. Summer of 2014.

A. Correct.

Q. So, since you testified in Mrs. Husky's case in the summer of 2014, have you done additional work that you rely on

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as the basis for your current opinions reflected in this expert report on the incidence of individual complications rate and the overall complication rate?
A. Well, of course. That's what this paper is.
Q. And this information wasn't available to you and you had not done this analysis at the time of Mrs. Husky's trial, correct?
A. Correct.
Q. Ethicon has made a statement that you may not -- I'm going to quote you: "Dr. Blaivas may not, quote, merely a year later, quote, purport to be certain about TVT complication rates."
Can you tell me why you can be certain about complication rates in August of 2015 when you couldn't be certain about complication rates in the summer of 2014?
A. Because we did such an exhaustive search of the literature and this is our best estimate of the minimum complication rate. I emphasize that.

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Q. And when you call it an estimate, it's an estimate that is based on two different scientifically reliable means for calculating the rates of complication; is that right?
A. Yes.
Q. And those are the ones that are reflected in Tables 2, 3, 4 and 5 of the report?
A. I'll take your word for it. Yes.
Q. I just want to make sure that I'm right.
A. Okay.
Q. Dr. Blaivas, do you believe that the conclusions that you reached in your report and in your Nature article assume the worst case scenario?
A. No. As I said, I think it assumes the best case scenario.
Q. And do you believe that it errs on the side of opining as to a higher complication rate to better protect a patient?

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A. No. I think if anything, it errs on the lower complication rate.
Q. And is that reflected in the fact that both the complication percentage and the incidence that you report out are lower than the highest rates that you saw in the research that you did?
A. Well, in part, but not --
MS. FITZPATRICK: Take a break.
(Discussion held off the record.)
MS. FITZPATRICK: Can you read back the question and answer?
(The requested portion of the record was read by the Court Reporter.)
A. Yeah, because we don't expect it to be the highest rate reported, but we know that the studies, that the majority of the studies don't follow the patient long enough to account for all the complications and that there's no registry and there isn't -- and they don't -- there isn't a methodology to specifically look for complications. So because of those three things alone, it's very likely that

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the complication rate that we reported is an underestimate of the real number of the complications.
Q. Now, Ethicon claims that your Review article cherry-picked data in failing to take into account long-term studies finding TVT complication rates to be much lower. And they then refer to the articles that are identified in Table 1 and states that at Table 1 of the article, the authors collected 11 studies purportedly meeting the criteria for inclusion.
Do those articles have to do with efficacy and your conclusions about efficacy, or do they have to do with the overall rates of complications?
A. The methodology was primarily geared towards efficacy.
Q. So, is it accurate to say that simply because something was not included in Table 1, it is incorrect for Ethicon to say that you did not take into account long-term studies that find TVT

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complication rates to be lower?
A. I'm sorry, there was a couple of negatives in there. I'm not sure about that.
Q. Okay. Ethicon attempts to use the fact that there were certain articles that you did not consider for efficacy as evidence that you did not use those articles for consideration of safety.
Is that accurate?
A. It's not accurate.
Q. Why not?
A. Because one thing I already alluded to is that we only counted the patients once. So if a patient -- I mean, for example, I know one of the articles in there -- when I say "know," let me just double check.
(Pause.)
For example, the Nielson article -- no, this doesn't answer your question. Excuse me.
The answer is "no" because some of the papers that they cited in that --

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in that deposition or, I think it was a deposition, were papers that were duplicate, so they used the same patients twice, and I already testified that when that happens, we only counted the complication once.
And the second thing is that if an article did not mention a complication, that it wasn't included. They didn't say that they even looked for it.
And then thirdly, I do remember, again I don't remember the specifics, but there was one or two articles that didn't come up in our search, and I don't know, you know, we did a very methodical search, but we searched thousands of papers and it's not unexpected that one or two wouldn't come up with a search.
Q. And is that something that routinely happens in peer-reviewed articles?
A. Sure.
Q. Does it call into question the reliability of a peer review article?

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A. I don't believe so.
Q. Now, defendants claim that your opinion that the TVT has a minimal complication rate takes into account prolapse devices.
Did you look at articles or consider statistics on prolapse devices when reaching your complication rate in this paper?
A. We did not look at -- if a paper had -- it's possible that some of the papers had patients with both prolapse and slings, but in the review process, we would have made our best effort to only include those patients that had to do with sling -- that where the complication was from a sling.
Q. Is it fair to say that Ethicon's claim that you included prolapse devices in calculating your complication rate is untrue?
A. To the best of our ability to make the distinction, it's untrue.
MS. FITZPATRICK: Can we go off

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the record for a second?
(Discussion held off the record.)
BY MS. FITZPATRICK:
Q. Dr. Blaivas, you participated in the committee at the AUA that considered the safety and efficacy of midurethral slings, correct?
A. Yes.
Q. Can you tell me what you did in that respect, what you personally did?
A. Well, we all -- it was a complicated process, similar to what I testified before. We did a literature search. We had inclusion criteria. We selected papers that had to do with the surgical management of urinary incontinence in women. We selected the papers and we tabulated the data on safety and efficacy, very similar to what we did in the Nature Review article for that column in the right where we looked at the incidence and the range. And we did that for all of the known treatments to stress incontinence at the time, surgical

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treatments.
Q. You didn't author those guidelines, correct?
A. Well, I was one of eleven authors.
Q. Do those guidelines reflect your personal opinions or the position of the AUA?
A. It reflected the opinions of the AUA.
Q. Did you disagree with some of those opinions?
A. Yeah, I disagreed with some of the conclusions.
Q. And did you express that during your meetings and to others?
A. I did.
Q. Is it fair to say that this though ended up being a consensus paper that doesn't fully and accurately reflect your personal views on the safety and efficacy of midurethral slings?
A. That's correct. I was one eleven -- I had one-eleventh of the vote.

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Q. Now, did the AUA conclude that mesh products are suitable surgical alternatives?
A. They did.
Q. What is your opinion as to whether mesh products are suitable surgical options?
A. I think they're suitable surgical options in a small percentage of patients who accept the known risks and complications and weigh the risks and benefits. But as I said, I contend that it's almost impossible to do that because those risks are not well-described and not well-known by either the doctors or the patients.
Q. When you say it's a suitable surgical option in, did you say a limited number of patients?
A. Yes.
Q. Can you tell me what you mean by that?
A. Well, I think in a -- first of all, in patients that are not going to

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be -- that have no intention of being sexually active and whose life expectancy isn't that long, so, you know, older women, particularly those that can't withstand the rigors of an open operation, that are not going to be sexually active, particularly those that are obese will be a much bigger operation to do an autologous sling. I think those patients are reasonable candidates once -- if they accept and are informed of the risks.
Q. Do you believe though that midurethral polypropylene slings are a safe first line surgical option for all women who suffer from stress urinary incontinence?
A. Well, I don't think it's my job to decide for another patient. I don't believe -- for the patient. I think the patient and the -- the patient needs to be informed of the risks and benefits, and if they were informed of the risks and benefits, I think they would realize that it's not safe and it's not worth the risk.

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I might not have answered. What was the actual question?
Q. You had said that you believed it was an appropriate surgical option for a limited number of patients. You identified who those patients were.
What I was asking was do you believe that the Ethicon midurethral slings are a suitable safe surgical option as a first line treatment for all women who have stress urinary incontinence?
A. I do not.
Q. And is that based on your clinical experience in treating women who have mesh-related complications?
A. Yes.
Q. And is it based --
A. Excuse me. And my knowledge of how likely they are to occur.
Q. Is it based on your review of the medical literature discussing the potential complications and the incidence of complications that are associated with midurethral slings?

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A. Yes.
Q. And that includes a review of literature that reports few complications and literature that reports many complications, correct?
A. Yes.
Q. And you take into account for your opinions medical articles that report low rates of complications when reaching your opinions, correct?
A. Yes.
Q. And you took all of those into account, to the best of your ability, when conducting your Nature Review, correct?
A. I did.
Q. And you didn't exclude any such reports simply because they had a low incidence of complication reported in them, correct?
A. Correct.
Q. Do you also base that opinion on your clinical experience in implanting autologous slings or doing non-mesh surgery for SUI patients?

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A. Yes.
Q. Do you also base your opinion on medical literature concerning the complications associated with the autologous fascial sling and other non-mesh surgeries to correct SUI?
A. I do.
Q. Now let's go back to the AUA.
Does the AUA recognize an autologous fascial sling as a suitable surgical option for women who have stress urinary incontinence?
A. It does.
Q. Does it recognize other non-mesh procedures as suitable surgical options for women who have stress urinary incontinence?
A. It does. Yes, it does.
Q. And what are those?
A. Autologous fascial sling, a Burch, it doesn't really -- also Marshall-Marchetti-Krantz, and other retropubic kind of operations and midurethral -- excuse me, periurethral

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injections, and homologous and xeno -- homologs and xenografts.
Q. Does the AUA conclude that the or look at --
MS. FITZPATRICK: Strike that.
Q. Does the AUA conclude that the polypropylene midurethral sling is a safer surgical option to some of the non-mesh surgeries?
A. It does not.
Q. And does the AUA guidelines that you were involved with suggest that physicians such as yourself and others should only consider polypropylene midurethral slings as a suitable surgical option for --
A. It does not.
Q. In that respect, do you agree with the AUA that these non-mesh procedures are suitable surgical options for women who have stress urinary incontinence?
A. Of course.
Q. Separate and apart from what's

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reflected in the AUA, do you believe that the non-mesh surgical options, and particularly the autologous fascial sling, are safer procedures for women who have stress urinary incontinence generally?
A. I do.
Q. Tell me what the basis for that opinion is.
A. Well, because the autologous slings simply don't have any of the devastating kind of complications that we talk about. For practical purposes, no refractory pain and there's, for practical purposes, no erosion, and for practical purposes, there's no fistulas. I mean, the really serious complications, the autologous sling does not have.
Q. Now, Ethicon has asserted that you base your opinions on the benefits of autologous slings solely on your own unreliable personal experiences.
Is that correct?
A. I wonder why they call my published peer-reviewed articles

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unreliable, but no, that's not correct.
Q. What else do you base it on?
A. The peer review literature and speaking with my associates.
Q. Okay.
A. My colleagues.
Q. Is there any specific -- let me ask you this.
When reaching your opinions concerning the safety of autologous fascial slings, did you consider all reported medical articles that you had seen concerning the complications rates associated with autologous fascial slings?
A. I did.
Q. And that formed one basis of your opinions, correct?
A. Yes.
Q. And you didn't simply adopt or form your opinion based on reading of a single article, correct?
A. Correct.
Q. Did you look at the totality of the articles out there that supported your

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opinions?
A. I looked at the totality, but I also looked at the severity of the complications and there's no question in my mind that the severity of the complications on average are much worse in synthetic slings than in autologous slings.
Q. Okay.
A. And also the ease with which they can be corrected are much easier and predict -- more predictable in the autologous sling compared to the mesh sling.
Q. Okay. Now, you offered opinions concerning mesh degradation, shrinkage and other deformation, correct?
A. Yes.
Q. Have you seen deformed mesh that you've explanted from women?
A. Of course.
Q. Have you seen mesh that's shrunk that you've explanted from women?
A. Well, I've seen the mesh scar

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complex.
Q. And mesh degradation, have you seen mesh falling apart when you take it out of women?
A. I have.
Q. Is your clinical experience in observing each of these phenomenon a basis for your opinion that each of those things can happen?
A. Yes.
Q. In addition to your clinical experience, is this an issue that you also studied in your Nature Review article?
A. Yes.
Q. Did you rely on the conclusions that you reached in your Nature Review article as a separate basis for your conclusions about mesh degradation, shrinkage and deformation?
A. I did.
Q. And can you tell me what you and your co-authors did to study mesh degradation, shrinkage, and deformation in your Nature Review article?

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A. Well, Dr. Latovlev actually that did that. I mean, he wrote that part of the article, and he himself has done extensive studies both of a explanted mesh looking at the gross specimen for stiffness and deformation, looking at the light microscopic and also the ultramicroscopic characteristics of the mesh, and he concluded based on his own work and that of many others in the literature that mesh degrades in vivo.
Q. Did he also conclude that mesh shrinks in vivo?
A. Yes.
Q. And did he also conclude that mesh can deform in vivo?
A. Yes.
Q. So you talked about what Dr. Latovlev did in your paper.
Is there additional literature in the peer review that you are aware of that establishes that mesh can degrade, shrink and deform?
A. Yes, there's a lot of -- there

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are a number of studies in the literature.
Q. Have you cited to those as part of your reliance list in this case?
A. I have.
Q. And those are the basis for your opinions?
A. Yes.
Q. I want to go back to just a general question.
Ethicon has raised questions about the methodology that you have used to reach your opinions in this case.
A. I'm sorry, I missed the first part of your sentence.
Q. Ethicon has raised issues with the methodology that you have used to reach your opinions in this case.
Did you rely on your clinical experience as part of your basis for each of the opinions that you hold?
A. I did.
Q. And did you rely on your own peer-reviewed literature as part of the basis for the opinions?

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A. I did.
Q. And did you rely on other peer review literature as part of the basis for your opinions in this case?
A. I did.
Q. Is it fair to say that each of your opinions depends on all three of those aspects of your experience as its bases?
A. It did, but when I heard your question, I'm trying to understand. There's no controversy about whether these things exist except for possibly the degradation. Everything's well documented in the literature. I think the only thing they could possibly contest is how often that occurs, but the published literature, exclusive of anything that I said, I mean, we -- you know, we cited the New England Journal of Medicine, the Journal of Urology, the most reputable journals, you know, show, for example, a five to six percent incidence of perforation. Every review article has shown one or two

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percent, at least, urethral obstruction, revision surgery. Those things are indisputable. There's no controversy about that.
The only thing -- the only thing they could possibly argue with is the actual incidence.
Q. And you've laid out for us what your methodology in calculating that incidence is, correct?
A. I think in much greater detail than any of the other articles that talk about complications.
Q. Let me just go back.
Now, Ethicon is not here at this deposition today, correct?
A. Correct.
Q. Now, this deposition was originally noticed by Ethicon, and you are here in deposition today because Ethicon asked you to be in deposition, correct?
A. Correct.
Q. And if Ethicon had chosen to show up for this deposition, they could

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have asked you any questions that they wanted based on your TVT-Exact report, correct?
A. Yes.
Q. And they chose not to do so today?
A. I believe so.
MS. FITZPATRICK: That's all that I've got.
I just would like to mark as Exhibit 2 the original notice of deposition of Dr. Blaivas from Ethicon that was dated August 25th, 2016.
(Blaivas Exhibit 2, Notice To Take Deposition of Jerry Blaivas, M.D. dated August 25, 2016, was marked for identification, as of this date.)
MS. FITZPATRICK: And mark as Exhibit 3 the amended notice to take the deposition of Dr. Blaivas that we filed today, August 29th, immediately following Ethicon's withdrawal of its notice.
(Blaivas Exhibit 3, Amended